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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,961	04/19/2001	Jewel Payne	MA-43CDF2D3	2884

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EXAMINER

BUGAISKY, GABRIELE E

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/03/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/837,961

Applicant(s)

PAYNE ET AL.

Examiner

Gabriele E. BUGAISKY

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 2-4,6-8,11-13,15-17 and 20-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,5,9,10,14,18,19 and 23 is/are rejected.
- 7) ☒ Claim(s) 1,10 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group IV in Paper No. 5 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 2-4, 6-8, 11-13, 15-17, and 20-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

The Examiner thanks Applicants for pointing out the inadvertent typographical error in the restriction requirement and for correctly surmising that each Group was directed to a different SEQ ID NO:.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Information Disclosure Statement***

Reference U9 of the IDS of paper #3 has not been considered as it is not a published patent document.

### ***Claim Objections***

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Claims 1, 10, and 19 are objected to because of the following informalities: they recite non-elected subject matter. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of controlling insects using microbial cells transformed to express a *B. thuringiensis* toxin of SEQ ID NO:8, does not reasonably provide enablement for a method of controlling insects using plant cells transformed to express a *B. thuringiensis* toxin of SEQ ID NO:8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims..

The effective filing date of this application is 1989; thus, one must ask whether the specification was considered enabling to the skilled artisan at that time.

In *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988). the issue of enablement in molecular biology was considered. There are eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those

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in the art; (g) the predictability of the art; and (h) the breadth of the claims. Although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable

The invention is directed to methods of controlling insects using microbial cells or plant cells that have been transformed to express the *Bacillus thuringiensis*  $\sigma$ -endotoxin gene encoding SEQ ID NO:8. The Examiner deems that a method of controlling insects using microbial cells transformed to express the *Bacillus thuringiensis*  $\sigma$ -endotoxin gene encoding SEQ ID NO:8. is sufficiently enabled, but that the enablement is insufficient for the full scope of the claims to extend to a method of controlling insects using or plant cells that have been transformed to express the *Bacillus thuringiensis*  $\sigma$ -endotoxin gene encoding SEQ ID NO:8.

The specification states on page 18, lines 25-29 and page 19, lines 1-3 that plant cells can be transformed with the *Agrobacter tumefaciens* Ti plasmid containing the gene of interest or the vector pEND4K containing the gene of interest. It is silent on how expression in plant cells is to be achieved so that one may kill insects using the plant cells expressing the toxin.

It was not, however, routine in the art at the effective filing date of the claimed invention to achieve expression of exogenous genes in plant cells. Special attention is drawn to Sutton *et al.* (1992), which not only discussed previous problems in achieving expression of *B.t.* crystal genes in plant cells, (see page 228, 1<sup>st</sup> paragraph of introduction,) but also showed that codon optimization is required for efficient expression of a  $\sigma$ -endotoxin gene in plant cells. This reference was only published several year after the 1989 effective filing date of the instant application.

In consideration of the above discussion of the *Wands* factors it is apparent that undue experimentation is required to obtain the claimed method of controlling insects using plant cells

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transformed to express the toxin of SEQ ID NO:8, . because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 10, 14 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear in claims 1, 10 and 19 what the "insecticidal fragments thereof" refers to- the claimed nucleotide or the encoded protein.

With respect to claims 10 and 14, an isolated polynucleotide cannot comprise an amino acid sequence. It is suggested that a portion of claim 10 was inadvertently omitted..

Claim 14 recites the limitation "said toxin" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 9-10, 14, 18-19 and 23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over all claims of U.S. Patent No.. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to SEQ ID NOs: , whereas the claims of the patent recite Figure numbers and specific plasmids. The identity of the claimed isolated polynucleotides and constructs, however, are the same in both the instant application and the patent, as they have been obtained from the 81A toxin gene. With respect to instant claims 19 and 23, it is obvious to use transformed microorganisms expressing an insecticidal toxin gene in a method of killing insects.

### ***Conclusion***

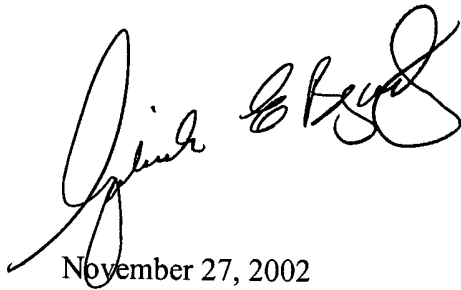
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15 AM- 2 PM, Tu & Th, 8:15 AM-1:30 PM, We & Fr.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.



November 27, 2002

Gabriele E. BUGAISKY  
Primary Examiner  
Art Unit 1653

**GABRIELLE BUGAISKY**  
**PRIMARY EXAMINER**